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EXAMINER
PATEL, JAGDISH

ART UNIT	PAPER NUMBER
3624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.		Applicant(s)	
Office Action Summary	09/490,019		BRAUNSTEIN ET AL.	
	Examiner		Art Unit	
	JAGDISH N PATEL		3624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>21 January 2000</u> .

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
   closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-25</u> is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-25</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

   If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____ .

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
          application from the International Bureau (PCT Rule 17.2(a)).
   * See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

   a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒	Notice of References Cited (PTO-892)	4) ☐	Interview Summary (PTO-413) Paper No(s). _____ .
2) ☐	Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐	Notice of Informal Patent Application (PTO-152)
3) ☐	Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) ☐	Other:

Specification

1.   The abstract of the disclosure is objected to because it contains more than 150

words. Correction is required. See MPEP § 608.01(b).

Claim Objections

2.   Claim 2 is objected to because of the following informalities:

The use of word "comprises" is misleading. It should read, "is". This is because

the server cannot not be included in a computer. The claim only clarifies that the

computer is a server (type). Appropriate correction is required.

Claim Rejections - 35 USC § 112

3.   The following is a quotation of the second paragraph of 35 U.S.C. § 112:.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject
matter which the applicant regards as his invention.

4.   Claims 3,4, 23 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. In particular,

A. Claims 23 and 24 are not sufficiently precise due to the combining of two separate

statutory classes of invention in a single claim. The preamble of the claim refers to an

apparatus, but the body of the claim and subsequently the claim then deals with the

specifics of a method by incorporation of method of claim 11.

To cure this problem each elements of method claim performed by the computer-

readable medium (claim 23) and elements of the portable health assistant that perform

each steps of claim 11 must be recites separately and explicitly.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

Claim 3 further limits claim 1. In particular step of "receiving the patient data

collected by the portable health assistant" at a computer remote from the portable

health assistant. This limitation does not further limit the subject limitation of claim 1.

Instead it further limits claim 1. The examiner interprets the claim as follows:

The method of claim 1 further comprising:

Receiving the patient data at a server ....;

At the remote computer, receiving ..... over a computer network.

Appropriate correction is required.

Claim 4 depends claim 3 and inherits same weakness as claim 3.

Claim Rejections - 35 USC § 101

5.   35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of

matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions

and requirements of this title".

6.   Claims 23 and 24 are rejected under 35 U.S.C. § 101 because the claimed

invention is directed to non-statutory subject matter.

35 USC 101 requires that in order to be patentable the invention must be a "new

and useful process, machine, manufacture, *or* composition of matter, *or* any new and

useful improvement thereof" (emphasis added). Applicant's claims mentioned above

are intended to embrace or overlap *two* different statutory classes of invention as set

forth in 35 USC 101. The claims begin by discussing a computer-readable medium (ex.

preamble of claim 23), the body of the claim then deals with the specifics of a method

(the steps) executed by the medical log (see above rejection of claims under 35 USC

112, second paragraph, for specific details regarding this issue). "A claim of this type is

precluded by the express language of 35 USC 101 which is drafted so as to set forth the

statutory classes of invention in the alternative only", Ex parte Lyell (17 USPQ2d 1548).

Claim Rejections - 35 USC § 102

7.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the
> United States before the invention thereof by the applicant for patent, or on an international application
> by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this
> title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act

of 1999 (AIPA) do not apply to the examination of this application as the application

being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35

U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8.   Claims 1-19 and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated

by Surwit et al. (US Pat. 6,024,699) (hereafter Surwit).

Claim 1. Surwit teaches a method for delivering health care through a

portable health assistant, comprising:

providing a patient with the portable health assistant (Portable Patient

Monitors (PPM) 12 , Fig. 1 and 2 and col. 6-7 System Overview)

configuring the portable health assistant with a protocol

comprising multimedia software content for treating a disease of the

patient through the portable health assistant (refer to TABLE1 col. 7 which list

functions and features of the PPM, col. 7 L 42-49, "software specifically designed for a particular

patient's illness);

at a computer remote from the portable health assistant,

receiving patient data collected by the portable health assistant in

accordance with the protocol (col. 9 L 25-34 remote computer (PAC server 14) receives the

data collected by the PPM 12);

from the remote computer, sending to the portable health

assistant an order, modifying how the protocol treats the disease, that

comprises a task that the portable health assistant reminds the patient to

perform at a predetermined time (col. 9 L 50-67, ..patient can be immediately notified via

communications from PAC server 14 to a PPM 12).

Claim 2.   The method of claim 1, wherein the remote

computer comprises a server that the portable health assistant periodically

accesses (col. 7 L 64 – col. 8 L 6 "regular basis" and "data transmissions using an alarm-driven timer", alternatively the portable device also accesses servers 16 CMC's as discussed in col. 6 L 28-47 and shown in Figure 1).

Claim 3.   The method of claim 1, further comprising:

receiving the patient data at a server remotely accessible by the portable health assistant (col. 10 L 25-46 patient data is received by case manager clients 16) ; and

at the remote computer, receiving a transfer of the patient data from the server to the remote computer over a computer network (col. 10 L 25-46, TCP/IP protocol over an Internet connection).

Claim 4.   The method of claim 3, wherein the computer network comprises an Internet and wherein receiving the transfer of the patient data from the server to the remote computer comprises receiving the patient data using a Web browser running on the remote computer (col. 10 L 25-46, refer to ISP).

Claim 5.   The method of claim 1, wherein sending to the portable health assistant the order comprises:
sending the order from the remote computer over a computer network to a server that is remotely accessible by the portable health assistant; and
sending the order from the server to the portable health assistant.

(col. 11 L 15-32, refer to discussion on communication among the PAC server 14,
CMC 16 and the PPM 12)

Claim 6.   The method of claim 5, wherein the computer network comprises an Internet and wherein sending the order from the remote computer over the computer network to the server comprises:

creating the order using an interface provided by the server through a Web browser running on the remote computer; and

through the Web browser, sending the order from the remote computer to the server. (refer to claim 5 analysis in view of col. 25-50)

Claim 7. The method of claim 1, further comprising receiving an alert at the remote computer that the patient data merits review by a clinician. (col. 9 L 59-67, medical emergency situations, a case manager can be notified...)

Claim 8.   The method of claim 7, wherein receiving the alert at the remote computer that the patient data merits review by the clinician comprises:

receiving the patient data at a server that is remotely accessible by the portable health assistant (col. 9 L 50-67 real-time analysis on the data... transmitted from a PPM);

determining at the server that the patient data matches predetermined criteria indicating that the patient data merits review by the clinician (col. 9 L 50-67 real-time analysis on data as it is being transmitted from a PPM... case manager can be notified); and

in response to determining at the server that the patient data matches the predetermined criteria, sending the alert over a computer network from the server to the remote computer (col. 9 L 50-67, Pac server identifies and prioritizes patient medical problems...).

Claims 9 and 10 .   The method of claim 1, wherein the patient data collected by the portable health assistant comprises an indicator of compliance by the patient with a treatment regimen associated with the protocol
      wherein the patient data collected by the portable health assistant comprises a symptom reported by the patient to the portable health assistant.
      (col. 7 L 42-63: refer to discussion on "patient data collected via a PPM).

Claim 11. Surwit discloses a computer-implement able method for providing health care under the supervision of a remote clinician, comprising:

      reminding a patient when to perform a task included in an order for treating the patient received from the clinician during a first periodic connection with a remote server (col. 8 L 36-55, a patient ..prompted to perform a task or a function).

      receiving from the patient an indication of a symptom experienced by the patient; and

      sending notification of the symptom to the remote server during a second periodic connection with the remote server so that the clinician can evaluate a need for a new order. (col. 11 L 15-32 and col. 7 L 15- col. 8 L 55).

Claim 12.   The method of claim 11, wherein receiving from the
patient the indication of the symptom experienced by the patient
comprises:

waiting for the patient to initiate reporting of the symptom;
and receiving the indication of the symptom from the patient.

(col. 7 L 64- col. 8 L 6, PPM has the ability to prompt patients when

data transmission is required)

Claim 13. The method of claim 11, wherein receiving from the patient
the indication of the symptom experienced by the patient comprises:

querying the patient to report the symptom; and

receiving the indication of the symptom from the patient (refer
also to analysis of claim 12, steps 100 and 200 Fig. 3, col. 11 L 60- col. 12 L 15).

Claim 14.   Surwit teaches the step of reminding the patient when to
perform the task included in the order as recited.

generating an audible alarm (col. 8 L 37-40, alarm initiated); and

providing instructions for performing the task to the patient (col.

8 L37-40 continuously informs the patient of his/her insulin dose ...).

Claim 15. The method of claim 14, wherein the instructions for
performing the task comprise multimedia information (Surwit, col. 8 L 7-10,
displaying text, graphics, prompts and various other information).

Claim 16. The method of claim 11, further comprising querying the patient to determine if the patient has completed the task (Surwit, col. 11 L 15-33, ..review ... all patient activity and data for ..assigned patients ... prescription review, analysis and adjustments).

Claim 17. The method of claim 16, further comprising notifying the remote server whether the patient has completed the task (Surwit, obtaining patient data as described in col. 12 L 15- end).

Claim 18. The method of claim 11, further comprising providing the patient with educational material about a disease of the patient (col. 7 L 60-63, disease-specific information to patients).

Claim 19. The method of claim 11, further comprising:

instructing the patient how to use a health-monitoring device; and receiving a physiological measurement of the patient determined by the health-monitoring device (col. 7 L 15-63).

Claim 21. The method of claim 19, wherein receiving the physiological measurement of the patient determined by the health monitoring device comprises receiving the physiological measurement through a direct connection with the health monitoring device (two-way communication with PAC serve, col. 7 TABLE 1 and col. 8 L 18-25, exemplary PPM 20 shows Glucose meter 26 directly connected to the PPM).

Claim 22.   The method of claim 11, further comprising:

receiving an indication that the patient wants to view the order;
and displaying the order to the patient (col. 8 L 64- col. 9 L 7).

Claims 23 and 24: analyzed as corresponding method claim 11.

Claim 25. All limitations of claim 25 are analyzed in independent
claims 1 and 11 combined.

Claim Rejections - 35 USC § 103

9.   The following is a quotation of 35 U.S.C. 103(a) which forms the
basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10.   Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable
over Surwit as applied to claim 19.

Claim 20: Surwit discloses the method for providing health care as
recited per claim 19. Surwit, however, fails to teach use of a touch
screen for entry of measurements..

It would have been an obvious matter of design choice to implement

a variety of interface including touch screen as a method for receiving

physiological measurement, since the applicant has not disclosed that

touch screen interface solves any stated problem or is for any particular

purpose and it appears that the invention would perform equally well with a

touch screen interface as with the interface recited in the referenced art.

Conclusion

11.   The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

   a.   WO 99/14882 (Peifer et al.) discloses a packet-based telemedicine

   system for communicating information between central monitoring stations and

   remote patient monitoring stations.

   a.   Dessertine (US Pat. 5,016,172) teaches a patient compliance and status

   monitoring system.

   b.   Webb (US Pat. 5,902,234) teaches a medical communication system for

   ambulatory Home-care patients.

   c.   Brown et al. (US pat. 6,032,119) discloses a personalized display of health

   information.

   d.   O'Brien (US Pat. 6,150,942) teaches an interactive prescription

   compliance and life safety system.

e.   Brown (US Pat. 6,334,778) discloses a remote psychological diagnosis

and monitoring system.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Jagdish Patel whose telephone number is (703) 308-
7837. The examiner can normally be reached Monday-Thursday from 8:00 AM to 6:00
PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Vincent Millin, can be reached at (703) 308-1038. The fax number for
Formal or Official faxes to Technology Center 3600 is (703) 305-7687. **Draft faxes
may be submitted directly to the examiner at (703) 746-5563**.

Any inquiry of a general nature or relating to the status of this application should

be directed to the Group receptionist whose telephone number is (703) 308-1113 or

308-1114. Address for hand delivery is 2451 Crystal Drive, Crystal Park 5, 7th Floor,

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JNP 09/16/02

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